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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,176	12/20/2005	Daria Onichtchouk	8138-005-US	1822

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CATALYST LAW GROUP, APC
9710 SCRANTON ROAD, SUITE S-170
SAN DIEGO, CA 92121

EXAMINER	
DESAI, ANAND U	

ART UNIT	PAPER NUMBER
1656	

MAIL DATE	DELIVERY MODE
07/09/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,176	ONICHTCHOUK ET AL.	
	Examiner	Art Unit	
	ANAND U. DESAI	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *3-8,11,15-18,21-27,29 and 31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,9,10,12-14,19,20,28,30 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 September 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20060123*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of group I in the reply filed on June 7, 2007 is acknowledged. Applicant's election of SEQ ID NO: 2 with traverse in the reply filed on June 7, 2007 is acknowledged. The traversal is on the ground(s) that there would not be a serious burden to search or otherwise examine the claims. The election of SEQ ID NO: 2 is traversed on the grounds that the relatedness of the species precludes the requirement of species, not withstanding possible patentable distinctness between species. Applicants state that electing one product out of the patentably distinct nucleic acid and polypeptide is improper in light of the relatedness between the various products. This is not found persuasive because the restriction is required under 35 U.S.C. 121 and 372 and the inventions are not so linked to form a single general inventive concept. The prior art cited in the election/restriction office action discloses the nucleic acid molecule and its amino acid sequence that is identical to applicants DG931 sequence and thus the unity of invention does not exist, because it does not define a contribution over the prior art. However, upon further review of group X, claim 32 drawn to a kit comprising a DG931 molecule this group is rejoined with the elected invention of group I, because it is drawn to a DG931 protein as is group I.

In addition, there is a serious search burden to examine patentably distinct inventions because as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide.

Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive. This search requires an extensive analysis of the art retrieved in a sequence search and will require an in-depth analysis of technical literature. As such, it would be burdensome to search the inventions together.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 15-18, and 21-26 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Claims 3-8, 11, 27, 29, and 31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected species of nucleic acid molecules, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on June 7, 2007.

3. Claims 1, 2, 9, 10, 12-14, 19, 20, 28, 30, and 32, drawn to a composition comprising SEQ ID NO: 2 that is a protein identified as DG931, are currently under examination.

Priority

4. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The priority date is March 31, 2003.

Information Disclosure Statement

5. The information disclosure statement (IDS) submitted on January 23, 2006 is being considered by the examiner. The retrieval date for the Genbank Accession number references

were added on the 1449 form based on the date listed at the bottom of each submitted copy of the respective Genbank citation. The foreign patent documents have not been considered because the disclosure fails to comply with 37 CFR 1.98(a)(2)(i). The documents are not present in the file history.

Specification

6. The disclosure is objected to because of the following informalities:

7. There is a typographical error on page 5, in the paragraph starting on line 17. The left quotations are shown as commas rather than quotation marks.

8. On page 7, line 11, the comma should be a period, when describing 99.6%.

9. On page 10, lines 8-9, the sentence is unclear.

Appropriate correction is required.

Claim Objections

10. Claims 9, 10, 12-14, 19, 20, 28, and 30 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 101

11. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

12. Claims 19 and 20 rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 19 and 20 encompass a transgenic human, which is drawn to non-statutory subject matter. Suggest an isolated recombinant host cell.

13. Claims 28 and 30 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

14. Claims 1, 2, 9, 10, 12-14, 19, 20, 28, 30, and 32 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility, a credible asserted utility or a well established utility.

The claims are drawn to a pharmaceutical composition comprising the DG931 protein or protein fragment. The composition is stated to be used for the preparation of a medicament for the treatment, alleviation, or prevention of metabolic diseases or dysfunctions, including diabetes, obesity, or metabolic syndrome. The disclosure states the invention advances the state of the art by providing previously unknown functions for a human secreted protein that has homology to cysteine-rich secreted proteins (see page 6, lines 2-4). The disclosure states DG931 functions in metabolism based on the analysis of the expression profile of the transcripts in different tissues and a role in adipocyte differentiation (see page 7, lines 20-22). The disclosure states that DG931 mRNA is significantly upregulated in several tissues, including muscle, brown adipose tissue (BAT), and white adipose tissue (WAT) supporting a role that DG931 is involved in the regulation of mammalian metabolism (see page 8, lines 14-19). The disclosure states that

DG931 protein has to be significantly downregulated in order for the preadipocytes to differentiate into mature adipocyte. The in vitro differentiation of 3T3-L1 displays a strong reduction in relative signal intensity of DG931, therefore the protein might play an essential role in adipogenesis (see page 8, lines 21-30). The disclosure states the general nonspecific use of microarrays to analyze differential display of nucleic acids for expression profiles (see page 9, lines 16-30). The disclosure states the general use of nucleic acids with expression vectors to transform host cells for recombinant protein expression (see page 12, beginning on line 1). The disclosure states the general use of peptides to generate antibodies using various mammalian host cells including goats, rabbits, rats, and mice (see page 16, line 33). The disclosure states the protein can be used as a pharmaceutical composition that can be administered by any number of routes (see page 21, line 15-18). The disclosure states the DG931 proteins can be used for screening libraries of compounds in any of a variety of drug screening techniques. One can identify effectors, e.g. receptors, enzymes, proteins, ligands, or substrates that bind to, modulate or mimic the action of one or more of the DG931 proteins (see page 27, lines 1-11).

However, the disclosure does not describe any specific, substantial, or credible metabolic diseases or dysfunctions that are affected by modulation of DG931 protein. The DG931 protein is not characterized such that a structure of the fragments or any isoforms will retain any particular function that could possibly function to treat any metabolic disease or dysfunction. The disclosure does not describe a credible manner of preventing any of the metabolic diseases or dysfunctions, including diabetes, obesity, or metabolic syndrome. Mazzone et al. disclose how accelerated atherosclerosis and cardiovascular disease in diabetes is likely to be multifactorial and therefore several therapeutic approaches can be considered (see abstract). It is

more credible that multiple pharmaceuticals will be administered to treat and/or prevent any of the broadly encompassed metabolic diseases or dysfunctions, such as diabetes, currently claimed rather than a single DG931 protein composition.

Claim Rejections - 35 USC § 112

15. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

16. Claims 19, 20, 28, and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

17. In claim 19, the phrase, "...expression of a DG931 polypeptide..." is unclear if the scope of the polypeptide was to "the DG931 polypeptide" or some unknown DG931 peptide sequence? Suggest replacing "a" with "the" and identifying the polypeptide with a SEQ ID NO:.

18. Claims 28 and 30 provides for the use of a polypeptide as defined in anyone of claims 1, 2, 9 or 10, or a host cell as defined in claim 19 or 20, respectively, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 112, First Paragraph, Written Description

19. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

20. Claims 1, 2, 9, 10, 12-14, 19, 20, 28, 30, and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are rejected under 35 U.S.C. 112, first paragraph, Written Description, because the disclosure does not direct one of ordinary skill in the art to any protein fragment that is a pharmaceutical composition. Claim 32 is also rejected because the disclosure does not direct one of ordinary skill in the art to any isoforms.

The Guidelines for Examination of Patent Applications under the 35 U.S.C. 112, Paragraph 1, "Written Description" Requirement, published at Federal Register, Vol. 66, No. 4, pp. 1099-1111 outline the method of analysis of claims to determine whether adequate written description is present. The first step is to determine what the claim as a whole covers, i.e., discussion of the full scope of the claim. Second, the application should be fully reviewed to understand how applicant provides support for the claimed invention including each element and/or step, i.e., compare the scope of the claim with the scope of the description. Third, determine whether the applicant was in possession of the claimed invention as a whole at the time of filing. This should include the following considerations: (1) actual reduction to practice, (2) disclosure of drawings or structural chemical formulas, (3) sufficient relevant identifying characteristics such as complete structure, partial structure, physical and/or chemical properties

and functional characteristics when coupled with a known or disclosed correlation between function and structure, (4) method of making the claimed invention, (5) level of skill and knowledge in the art and (6) predictability of the art. For each claim drawn to a single embodiment or species, each of these factors is to be considered with regard to that embodiment or species. For each claim drawn to a genus, each of these factors is to be considered to determine whether there is disclosure of a representative number of species that would lead one skilled in the art to conclude that applicant was in possession of the claimed invention. Where skill and knowledge in the art is high adequate written description would require fewer species to be disclosed than in an art where little is known; further, more species would need to be disclosed to provide adequate written description for a highly variable genus.

First, what do the claims as a whole cover? Claim 1 is drawn to a pharmaceutical composition comprising any protein fragment of DG931 protein. Dependent claims encompass the protein fragment without further describing the structure of the fragment that confers the pharmaceutical function intended.

Second, how does the scope of the claims compare to the scope of the disclosure? The disclosure discloses the structure of a full-length DG931 protein identified as SEQ ID NO: 2, however there is no characterization of any isoforms or fragments with any function.

Third, the factors need to be considered.

(1) What was actually reduced to practice?

The cloning of DG931 was reduced to practice. RNA quantification for the DG931 transcript was performed using TaqMan anaylsis.

(2) Is there disclosure of drawings or structural chemical formulas?

There is no disclosure of how any particular structure gives rise to any function for DG931.

(3) Are there sufficient relevant identifying characteristics disclosed?

Insufficient relevant identifying characteristics are provided by the instant disclosure. There is no disclosure of any isoforms or fragments that would confer any particular function to any amino acid sequence. There is no disclosure for the full-length protein with any function.

(4) Is there at least one method of making the claimed invention disclosed?

Given the structure of the amino acid sequence, basic molecular biological techniques could be used to in vitro express the protein.

(5) What knowledge is present in the art? / (6) What is the level of predictability of the art?

The ability of cloning and expressing nucleic acid sequences has reached a matured state in the art of molecular biology. However, the level of predictability in this art is very low since, until the polypeptide is characterized, there is no information upon which to base a prediction of what the protein or fragments may do in a cellular environment in any particular cell.

Thus, having analyzed the claims with regard to the Written Description guidelines, it is clear that the specification does not disclose a representative number of species which would lead one skilled in the art to conclude that applicant was in possession of the claimed invention of any isoforms or fragments.

Claim Rejections - 35 USC § 112, 1st paragraph, enablement rejection

21. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

22. Claims 1, 2, 9, 10, 12-14, 19, 20, 28, 30, and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are rejected because of undue experimentation to practice the claimed method for the genus of peptides encompassed by isoforms and fragments. The undue experimentation arises due to the unpredictability based on the differing conditions of starting materials, such as the different structures of the peptides encompassed by the claims. The claims are also rejected for the scope of preventing any metabolic disease or dysfunction as currently encompassed by claim 14.

In *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988) eight factors should be addressed in determining enablement.

While the analysis and conclusion of a lack of enablement are based on the factors discussed in MPEP § 2164.01(a) and the evidence as a whole, it is not necessary to discuss each factor in the written enablement rejection. The language should focus on those factors, reasons, and evidence that lead the examiner to conclude that the specification fails to teach how to make and use the claimed invention without undue experimentation, or that the scope of any enablement provided to one skilled in the art is not commensurate with the scope of protection sought by the claims. This can be done by making specific findings of fact, supported by the evidence, and then drawing conclusions based on these findings of fact. For example, doubt may

arise about enablement because information is missing about one or more essential parts or relationships between parts which one skilled in the art could not develop without undue experimentation. In such a case, the examiner should specifically identify what information is missing and why one skilled in the art could not supply the information without undue experimentation. See MPEP § 2164.06(a). References should be supplied if possible to support a prima facie case of lack of enablement, but are not always required. *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). However, specific technical reasons are always required.

1) The nature of the invention: the instant claims are directed to a pharmaceutical composition comprising any protein fragment of DG931 protein. Dependent claims encompass the protein fragment without further describing the structure of the fragment that confers the pharmaceutical function intended. The claims are also drawn to a use of the genus of peptides for the treatment, alleviation or prevention of metabolic diseases or dysfunctions, including diabetes, obesity, or metabolic syndrome.

3) The predictability or unpredictability of the art: & 6) The quantity of experimentation necessary: & 7.) The state of the prior art: the prior art has shown a large quantity of experimentation is often necessary to overcome the unpredictable nature of preventing a disease or dysfunction. Mazzone et al. disclose how accelerated atherosclerosis and cardiovascular disease in diabetes is likely to be multifactorial and therefore several therapeutic approaches can be considered (see abstract). Therefore, the unpredictability arises due to the differing conditions of various metabolic diseases or dysfunctions and whether a single modality would or could prevent the various metabolic diseases or dysfunctions. There would be a large quantity of

experimentation necessary to determine what metabolic diseases or dysfunctions can be treated and/or prevented with what protein fragments or isoforms if at all.

4) The amount of direction or guidance presented; & 5) The presence or absence of working examples: the specification is devoid of any examples that prevent or treat metabolic conditions, including diabetes and obesity with the administration of DG931 or any fragments, or isoforms thereof.

8.) Level of skill in the art: the level of skill in this art of developing pharmaceutical compositions is high and unpredictable.

In consideration of the Wands factors, it is apparent that there is undue experimentation because of variability in prediction of outcome that is not addressed by the present application disclosure, examples, teaching, and guidance presented. Absent factual data to the contrary, the amount and level of experimentation needed is undue.

23. Claims 1, 2, 9, 10, 12-14, 19, 20, 28, 30, and 32 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility, a credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 102

24. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

25. Claims 1, 2, 9, 10, 12-14, 19, 20, and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Agarwal et al. (WO 02/22802 A1).

Agarwal et al. disclose an amino acid sequence with 100% identity to SEQ ID NO: 2. The sequence is identified as SEQ ID NO: 68 in the WO 02/22802 reference (see page 24, page 163, claims 1, 3, 5, and alignment below). Agarwal et al. disclose the recombinant production of polypeptides using well known processes of transforming host cells, including human HeLa cells (see page 9, lines 6-26, and claims 3-5, and 7). Agarawal et al. disclose the use of the protein for treatment of diseases (see page 3, lines 12-14). In addition, the kit of claim 32 is drawn to a product comprising the DG931 amino acid molecule, which is disclosed by Agarwal et al.

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Query Match             100.0%;  Score 2760;  DB 6;  Length 497;
Best Local Similarity   100.0%;  Pred. No. 3.3e-241;
Matches  497;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy          1 MSCVLGGVIPLGLLFLVCGSQGYLLPNVTLLEELLSKYQHNESHSRVRRAIPREDKEEIL 60
              |||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          1 MSCVLGGVIPLGLLFLVCGSQGYLLPNVTLLEELLSKYQHNESHSRVRRAIPREDKEEIL 60

Qy         61 MLHNKLRGQVQPQASNMEYMTWDDELEKSAAAWASQCIWEHGPTSLLVSIGQNLGAHWGR 120
              |||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         61 MLHNKLRGQVQPQASNMEYMTWDDELEKSAAAWASQCIWEHGPTSLLVSIGQNLGAHWGR 120

Qy        121 YRSPGFHVQSWYDEVKDYTYPYPSECNPWCPERCSGPMCTHYTQIVWATTNKIGCAVNTC 180
              |||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
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Qy        181 RKMTVWGEVWENAVYFVCNYSPKGNWIGEAPYKNGRPCSECPPSYGGSCRNNLCYREETY 240
              |||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        181 RKMTVWGEVWENAVYFVCNYSPKGNWIGEAPYKNGRPCSECPPSYGGSCRNNLCYREETY 240
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Qy       241 TPKPETDEMNEVETAPIPEENHVWLQPRVMRPTKPKKTSAVNYMTQVVRCDTKMKDRCKG 300
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       241 TPKPETDEMNEVETAPIPEENHVWLQPRVMRPTKPKKTSAVNYMTQVVRCDTKMKDRCKG 300

Qy       301 STCNRYQCPAGCLNHKAKIFGTLFYESSSSICRAAIHYGILDDKGGLVDITRNGKVPFFV 360
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       301 STCNRYQCPAGCLNHKAKIFGTLFYESSSSICRAAIHYGILDDKGGLVDITRNGKVPFFV 360

Qy       361 KSERHGVQSLSKYKPSSSFMVSKVKVQDLDCYTTVAQLCPFEKPATHCPRIHCPAHCKDE 420
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       361 KSERHGVQSLSKYKPSSSFMVSKVKVQDLDCYTTVAQLCPFEKPATHCPRIHCPAHCKDE 420

Qy       421 PSYWAPVFGTNIYADTSSICKTAVHAGVISNESGGDVDVMPVDKKKTYVGSLRNGVQSES 480
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       421 PSYWAPVFGTNIYADTSSICKTAVHAGVISNESGGDVDVMPVDKKKTYVGSLRNGVQSES 480

Qy       481 LGTPRDGKAFRIFAVRQ 497
             |||||||||||||||||
Db       481 LGTPRDGKAFRIFAVRQ 497
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Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433. The rejected claims are drawn to a product that are disclosed by Agarwal et al.

Conclusion

26. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANAND U. DESAI whose telephone number is (571)272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on (517) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

July 1, 2008

/Anand U Desai, Ph.D./
Patent Examiner, Art Unit 1656